UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,782	04/03/2006	Terrence C. Dahl	269.PFUS	7169

25000 7590 11/18/2008

GILEAD SCIENCES INC
333 LAKESIDE DR
FOSTER CITY, CA 94404

EXAMINER
ZAREK, PAUL E

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
11/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,782	DAHL ET AL.	
	Examiner	Art Unit	
	Paul Zarek	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) *10 and 24-57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 11-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-57 are currently pending. This is the first Office Action on the merits of the claim(s).

Election/Restrictions

2. Applicant's election of Group I and emtricitabine in the reply filed on 10/01/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1-9 and 11-23 read on the elected species. Claim 10 is withdrawn as being drawn to a nonelected species. Claims 24-57 are withdrawn as being drawn to a nonelected invention.

Priority

3. Applicant's claim for the benefit of a prior-filed international application PCT/US04/00868 (filed on 01/13/2004) which claims the benefit of provisional applications 60/440,246 and 60/440,308 (both filed on 01/14/2003) under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. The effective filing date of the instant application is 01/14/2003.

Information Disclosure Statement

4. Examiner notes that no IDS has been submitted with the instant application.

Claim Rejections - 35 USC § 112 (1st paragraph)

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-9 and 11-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating the symptoms or effects of HIV infection comprising the administration of GS-7340 and emtricitabine, does not reasonably provide enablement for the prevention of the symptoms or effects of HIV infection comprising the administration of GS-7340 and emtricitabine, or treatment of HIV comprising physiologically functional derivatives of GS-7340 and emtricitabine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

7. *In re Wands*, 858 F.2d at 736-40, 8 USPQ2d at 1403-07, set forth eight factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." (MPEP § 2164.01(a))

a. *The breadth of the claim*: The rejected claims are drawn to a method of treating or preventing the symptoms or effects of HIV infection comprising the administration of a

composition comprising GS-7340 and emtricitabine or physiologically functional derivatives thereof. Symptoms of HIV infection include the infection of cells by HIV. Effects of HIV infection include transmission of the virus to another individual.

The specification defines "physiological functional derivative" as any physiological acceptable salt, ether, ester, prodrug, solvate, stereoisomer or any other compound that becomes the active metabolite of GS-7340 or emtricitabine (instant specification, pg 6, lines 9-17). This includes all compounds known and as yet undiscovered.

"Prevent" and "prevention" are potent terms implying that the method of prevention will necessarily prevent HIV from infecting any cell in a subject at any point following administration of GS-7340 and emtricitabine. Accordingly, if even one cell becomes infected with HIV, the method is no longer considered a prevention method;

b. *Nature of the invention*: The nature of the invention is drawn to a method of treating, but not preventing, the symptoms or effects of HIV infection, comprising administration of GS-7340 and emtricitabine;

c. *The state of the prior art*: GS-7340 is the prodrug of tenofovir (a nucleotide reverse transcriptase inhibitor), and possesses preferable pharmacokinetics to tenofovir as it has better oral bioavailability due to its enhance cell permeability characteristics (Eisenberg, et al., Nucleosides Nucleotides Nucleic Acids, 2001, abstract). Eisenberg, et al., also disclose that GS-7340 is converted to the active metabolite PMPApp, *in vivo*, and possess anti-HIV activity. Emtricitabine (or FTC) is a nucleoside reverse transcriptase

inhibitor that has undergone Phase III trials for HIV treatment (DeClerq, Current Medicinal Chemistry, 2001, pg 1554, paragraph 2, lines 6-7).

Currently, there is no known prevention therapy for HIV infection. Merson, et al., teach that a successful prevention protocol would require numerous interventions, including behavioral, structural, and biomedical approaches (The Lancet, 2008, pg 475, "Key messages"). Avert.org discloses the difficulties associated with developing an effective AIDS vaccine. These include the ability of HIV to insert its genetic material in a host cell, its high variability and ability to quickly evolve, and the fact that there are no good animal models upon which to test potential vaccine therapies (pg 2). Although these difficulties are directed to development of an AIDS vaccine, one of ordinary skill would recognize that these same barriers confront those attempting to develop pharmacologic preventative measures against HIV and HIV infection.

Byrn, et al. (Solid State Chemistry of Drugs, 1999), teach that "[t]he occurrence of hydrated or solvated crystal forms, crystals in which solvent molecules occupy regular positions in the crystal structure, is widespread but by no means universal among drug substances." (pg 232, emphasis added). Most drug crystals that fall into the category of solvates are hydrates (pg 236).

Byrn, et al., note that the water molecule is particularly suited to fill structural voids, due to its small size. In hydrated crystal structures, water molecules bind to other water molecules but also to any available functional group, i.e. carbonyls, amines, alcohols, and many others which are capable of accepting or donating an active hydrogen atom to form hydrogen bonds (pg 236, "Hydrates"). Also, the behavior of hydrates of

pharmaceuticals is unpredictable due to dehydration prior to melting, and cracking during dehydration (pg 234). Also hydrates and solvates may only be formed under certain conditions, dependent upon the compounds sought to be crystallized. Such a process is not a given in pharmacology and requires a great deal of research, with no guarantee of success.

Furthermore, the stability of solvates and hydrates is not altogether predictable, wherein said stability directly affects the properties of a given molecule. This lack of stability means a hydrate or solvate, if found to possess similar properties as the target compound, may not function as intended, *in vivo*. Such facts lead to the conclusion that more than a mere recitation is needed in order to support a claim to solvates and hydrates. Creating functional solvates and hydrates with the same properties as the mother-compound is by no means routine, thus there must be a showing sufficient to satisfy the enablement requirement;

d. *Level of one of ordinary skill in the art*: The level of one of ordinary skill would be high. It would include physicians and researchers investigating the epidemiology and cell and molecular biology of HIV;

e. *Level of predictability in the art*: Both GS-7340 and emtricitabine are known to be reliable treatments for HIV. Byrn, et al., disclose that the properties of solvates and hydrates of a given drug can only be determined empirically;

f. *Amount of direction provided by the inventor*: Applicant contends that GS-7340 and emtricitabine are effective anti-HIV drugs and cite references in support of this contention. Applicant further asserts that the two drugs may work synergistically with

each other. Applicant provides no data regarding the anti-HIV activity of GS-7340 and emtricitabine; rather, there is Applicant discloses how one of ordinary skill in the art would determine whether derivatives of GS-7340 and emtricitabine would be anti-HIV drugs. Applicant further provides various formulations which comprise GS-7340 and emtricitabine. Applicant has provided no guidance for determining which drug would be a physiological functional derivative of either GS-7340 or emtricitabine;

g. *Existence of working examples*: Applicant provides no working examples; and,

h. *Quantity or experimentation needed to make or use the invention based on the content of the disclosure*: GS-7340 and emtricitabine are known anti-HIV drugs with established mechanisms, and have been used independently to treat HIV infection (Eisenberg, et al., and DeClerq, above). However, the instant specification provides no guidance for one of ordinary skill in the art to determine whether a given compound would be a physiological functional derivative of either GS-7340 or emtricitabine. Such a derivative is not defined by its manufactured structure, but by how it gets metabolized, *in vivo*. Byrn, et al., disclose that the properties of solvates and hydrates of a given drug can only be determined empirically, so one of ordinary skill in the art could not know whether a given compound would be a functional derivative of GS-7340 or emtricitabine without unpredictable experimentation.

There are currently no known methods to prevent symptoms or effects of HIV infection. The art provides guideposts for one of ordinary skill to develop a prevention method, but such methods require a multidisciplinary approach (Merson, et al.). Furthermore, even to develop a pharmacological prevention method, one of ordinary skill

would have to create an entirely new field of research, including the development of currently nonexistent animal models and a method to reliably predict and inhibit HIV's ability to evolve around the prevention method (Avert). If, upon first try, the development of a prevention method was unsuccessful, which would be likely given the complexity of preventing HIV symptoms or effects, one of ordinary skill in the art would have to develop new drugs or new experimental methods. Neither the specification nor the art provide sufficient guidance for a skilled artisan to overcome the experimental obstacles. Undue and unpredictable experimentation would be required to make and use the invention as claimed. Therefore, the instant specification does not enable one of ordinary skill in the art to use the invention commensurate with the scope of the rejected claims.

Claim Rejections - 35 USC § 112 (2nd paragraph)

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-9 and 11-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejected claims are drawn to a method of treating or preventing the symptoms or effects of HIV infection comprising the administration of a composition comprising GS-7340 and emtricitabine or physiologically functional derivatives thereof. The specification defines "physiological functional derivative" as any physiological acceptable salt, ether, ester, prodrug, solvate, stereoisomer or any other compound that becomes

the active metabolite of GS-7340 or emtricitabine (instant specification, pg 6, lines 9-17). Such compound could not be determined without assessing whether the compound is converted to the same active metabolite to which either GS-7340 or emtricitabine are converted. Therefore, the metes and bounds of the rejected claims are indefinite.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-9 and 11-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eisenberg, et al. (above) and DeClerq (above) in view of Arimilli, et al. (US Patent No. 6,069,249, 2000), Liotta, et al. (US Patent 5,814,639, 1998), Maye, et al. (US Patent No. 6,113,920, 2000), and Rich and Solomon (US Patent No. 6,270,957, 2001).

13. Claims 1 and 9 are drawn to a method of treating or preventing the symptoms or effects of HIV infection in an infected animal comprising administration of a composition comprising GS-7340 and emtricitabine (the elected species of Claim 9), or a physiologically functional derivative of either or both GS-7340 and emtricitabine. Claim 2 limits the combination to GS-7340 and emtricitabine. Claim 3 limits the doses of GS-7340 and emtricitabine to 150 mg and 200 mg, respectively. Claims 4 and 5 limit the weight ratio of GS-7340 and emtricitabine to between about1:50 and about 50:1 (Claim 4) or between about 1:10 and about 10:1 (Claim 5). Claims 6 and 7 limit the dosage of GS-7340 and emtricitabine in unit dosage form to between about 1 and 1000 mg (Claim 6) or between about 100 mg and 300 mg (Claim 7). Claim 8 limits GS-7340 to a fumarate salt. Claim 11 limits the emtricitabine to a racemic mixture of emtricitabine. Claims 12-15 limit the physiologically functional derivative of GS-7340. GS-7340 is embodied by Claims 12-15. Claims 16-18 limit the dosing order (sequentially, Claim 16) and formulation (single, combined, Claims 17 and 18). Claims 18 and 19 limit the subject treated to a human. Claims 20 and 21 further limit the composition of Claim 1 to include a third active ingredient (Claim 20), specifically tenofovir disoproxil fumarate (Claim 21). Claims 22 and 23 further limit the composition of Claim 1 to include a glidant (Claim 22), specifically calcium, magnesium, or zinc stearate, or combinations thereof (Claim 23).

14. Eisenberg, et al., teach that GS-7340 is the prodrug of tenofovir (PMPA), a nucleoside analog and known anti-HIV drug. GS-7340 is highly bioavailable, stable in plasma, demonstrates that the active intracellular metabolite, (PMPApp) is proportional to GS-7340 dosage (abstract), and possesses anti-HIV activity in cell culture. Eisenberg, et al, do not teach

combining GS-7340 with emtricitabine, a dose of GS-7340, presence of an additional active ingredient to the treatment regimen, or the presence of a glidant.

15. DeClerq teaches that emtricitabine ((-)FTC) is a nucleotide reverse transcriptase inhibitor that can be used to treat HIV infections in humans (pg 1554, paragraph 2, lines 6-7). DeClerq also teaches that combinations of emtricitabine (an NRTI) with nonnucleotide reverse transcriptase inhibitors (NNRTIs) and protease inhibitors (PIs) are effective treatments for HIV infected patients suffering AIDS (pg 1543, col 2, paragraph 2, lines 1-15). DeClerq does not disclose specific dosages, combining emtricitabine with GS-7340 or tenofovir, specifically, or the presence of a glidant. However, combining two drugs that are known to treat the same disease is not a patentably distinguishing feature of an invention. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (MPEP § 2144.06(I). Tenofovir disoproxil fumarate (Claim 21) is known a known NRTI. Therefore, it would have been *prima facie* obvious to add tenofovir disoproxil fumarate to the composition comprising GS-7340 and emtricitabine. DeClerq limits his discussion of emtricitabine to (-)FTC, where Claim 11 of the instant application is drawn to the racemic mixture of emtricitabine. Absent evidence to the contrary, one of ordinary skill in the art would reasonably expect that a specific stereoisomer of emtricitabine would be the functional equivalent to a racemic mixture of emtricitabine. "A *prima facie* case of obviousness may be made when chemical compounds have very close structural similarities and similar utilities. 'An obviousness rejection based on

similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties.' *In re Payne*, 606 F.2d 303, 313, 203 USPQ 245, 254 (CCPA 1979)" (MPEP § 2144.09(I).

16. Amirilli, et al., disclose pharmacokinetic profiles of various tenofovir (e.g. PMPA) prodrugs (Table 1). Amirilli, et al., do not disclose the pharmacokinetic profile of GS-7340 specifically. Liotta, et al., teach effective doses of FTC (emtricitabine) with the preferred dose being 1-20 mg/kg/day (col 17, lines 5-7). For a person having a mass of 80 kg (176 lbs), daily dose of 200 mg of emtricitabine (as in Claim 3) would be the equivalent of 2.5 mg/kg/day. Neither Amirilli, et al., nor Liotta, et al., specifically teach a weight ratio between GS-7340 and emtricitabine. However, the prior art provides guidance that would allow one of ordinary skill in the art to determine an appropriate dose of both GS-7340 (by using the pharmacokinetic profile of other tenofovir prodrugs) and entricitabine, together. The knowledge of the pharmacokinetics of both drugs would also allow a skilled artisan to construct a dosing schedule Such a determination, then, would be considered an optimization of the prior art through routine experimentation. "Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. '[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.' *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)" (MPEP § 2144.05(II)).

17. Maye, et al., disclose pharmaceutical compositions comprising lamivudine, zidovudine and a glidant for the inhibition of HIV. The glidant used in the formulation of Maye, et al., include metallic stearates, including calcium, stearate, magnesium stearate and zinc stearate (col 5, lines 3-7). Maye, et al., also teach that it is possible to combine two NRTIs in a single oral formulation (Example I). Lamivudine and zidovudine are both NRTI, as are GS-7340 and emtricitabine, and it would be reasonable to expect that both groups would utilize similar glidants. Rich and Solomon teach that fumarate salt is a pharmaceutically acceptable salt for oral formulation (col 65, lines 4-7). Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the methods of treating HIV infection taught by Eisenberg, et al., and DeClerq for a single treatment for symptoms or effects of HIV infection. One of ordinary skill would have been further guided by Amirilli, et al., Liotta, et al., Maye, et al., and Rich and Solomon to incorporate various dosage amounts and scheduling, the presence of a glidant, and the use of the fumarate salt of GS-7340.

Double Patenting

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 1, 2, 9, 11-15, 22, and 23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 59 and 70-72 of copending Application No. 10/540,794 in view of Eisenberg, et al. (above). Claims 1, 2, 9, and 11-15 of the instant application are drawn to a method of treating HIV infections comprising administration of GS-7340 and emtricitabine. Claims 22 and 23 further limit the composition to include specific glidant(s). Claim 59 of the '794 application is drawn to a method of treating HIV comprising the administration of a composition comprising tenofovir disoproxil fumarate and emtricitabine. Claims 70-72 further limit the composition to include a glidant. Eisenberg, et al., teach that GS-7340 is the prodrug of tenofovir (PMPA), a nucleoside analog and known anti-HIV drug. GS-7340 is highly bioavailable, stable in plasma, demonstrates that the active intracellular metabolite, (PMPApp) is proportional to GS-7340 dosage (abstract), and possesses anti-HIV activity in cell culture. One of ordinary skill would recognize that it would be advantageous to replace a given drug (i.e. tenofovir disoproxil fumarate) with a prodrug (i.e. GS-7340), in which the prodrug displays preferable pharmacokinetics. The glidants specified in Claims 22 and 23 of the instant application are the same as those listed in Claims 70-72 in the '794 patent application.

This is a provisional obviousness-type double patenting rejection.

Conclusion

20. No claims are allowed.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Zarek whose telephone number is (571) 270-5754. The examiner can normally be reached on Monday-Thursday, 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PEZ

/Rita J. Desai/
Primary Examiner, Art Unit 1625